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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/634,049	08/04/2003	Jose Luis Francese	MED-015	5515
36822	7590	10/02/2006	EXAMINER	
GORDON & JACOBSON, P.C. 60 LONG RIDGE ROAD SUITE 407 STAMFORD, CT 06902			NGUYEN, TUAN VAN	
			ART UNIT	PAPER NUMBER
			3731	

DATE MAILED: 10/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/634,049

Applicant(s)

FRANCESE ET AL.

Examiner

Tuan V. Nguyen

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) 33-42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-32 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>12/15/03</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-32, drawn to a surgical port device, classified in class 606, subclass 231.
 - II. Claims 33-42, drawn to method of using surgical port device, drawn to class 128, subclass 898.

The inventions are distinct, each from the other because of the following reasons:

Inventions II and I are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the process as claimed can be practiced by another and materially different apparatus that does not have to have a flexible flange.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least

one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

2. A telephone call was made to Mr. Jay Sbroolini (Reg. No. 36,266) on September 11, 2006 to discuss the above restriction requirement. The result was a provisional election was made to prosecute the invention of Group I, drawn to surgical port device, claims 1-32. Affirmation of this election must be made by applicant in replying to this Office action. Claims 33-42 withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. **Claims 1-9 and 13-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Aboul-Hosn (U.S. 6,228,063).**
5. Referring to **claims 1-9 and 13-15**, Aboul-Hosn discloses (see Figs. 2-5) an surgical port device 10 for insertion through a body wall, comprising: a cylindrical elongated member 12, which made of polymer of stainless steel, or port body 12 including a tubular section having a distal 14 end and a flexible flange 22 disposed at said distal end; a retention member 80 that is slidably mated along said tubular

section such that a distance between said retention member and said flexible flange can be adjusted, whereby said retention member and said flexible flange cooperate to clamp portions of the body wall 8 disposed therebetween and thus effectively clamp said port body in place; flexible flange 22, that made of silicone, is adapted to reduce in diameter when said port body passes through a narrow opening in the body wall (see Fig. 2A) and said flexible flange 22 has a frusto-conical shape with a proximally-concave outer surface and the flange includes an annular projection that projects radially outward wherein the projection is mating with the obturator 77 (see Fig. 3); obturator 77 having a rod-like section 75, tip 74, and handle 73 (see Fig. 2B); and a valve assembly 47 at the proximal end of cylindrical member 12 (see col. 4, line 12 to col. 6, line 45). Here it is noted that silicone material is a hydrophobic material. Adding weight to examiner statement U.S. Patent No. 3,983,879 issued to Todd discloses silicone is a hydrophobic material (see col. 2, lines 43-45).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
8. **Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Aboul-Hosn in view of Freitas et al. (U.S.5,330,497).**
9. Referring to claim 10, Aboul-Hosn discloses the invention substantially as claimed except for the cylindrical elongated member 12 has plurality of grooves on the outer surface that mating with the retention member wherein the grooves resists the retention member sliding in a proximal direction. Freitas discloses (see Figs 8, 9, and 10) a locking trocar sleeve having retention member 72 and the cylindrical elongated member 170 has plurality of grooves on the outer surface that mating with the retention member wherein the grooves resists the retention member sliding in a proximal direction (see col. 7, lines 9-45). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made by the applicant to use the retention design, as disclosed by Freitas, to incorporate into the device, as disclosed by Aboul-Hosn because this will provide another failsafe feature beside suturing.
10. **Claims 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aboul-Hosn in view of Loeffler (U.S. 2,064,435).**

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11. Referring to claims 11 and 12, Aboul-Hosn discloses the invention substantially as claimed except for the tubular member having at least one window therein. Loeffler discloses a technique for reinforcement of a molded article wherein the reinforcement having plurality of holes for facilitate the flow of molding composition through (see page 1, lines 42-50). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made by the applicant to use the molding technique, as disclosed by Loeffler, to incorporate into the device, as disclosed by Aboul-Hosn to gain the advantages as suggested by Loeffler.
12. **Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Aboul-Hosn in view of Shikhman et al. (U.S. 5,423,796).**
13. Referring to claim 16, Aboul-Hosn discloses the invention substantially as claimed except for a side port in fluid communication with said passage of the cylindrical elongated member. Shikhman discloses (see Fig. 1) a trocar system having side port 60 wherein the port 60 in fluid communication with the central passage of the trocar sleeve 24 for the purpose of insufflation and desufflation (see col. 5, lines 1-5) Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made by the applicant to add the side port, as disclosed by Shikhman, to incorporate into the device, as disclosed by Aboul-Hosn to gain the advantages of insufflation and desufflation as suggested by Shikhman. Here it is noted that side port for insufflation and desufflation in a trocar system is old and well known in the art.

14. **Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Aboul-Hosn in view of Worner (U.S. 2,320,993).**
15. Referring to claim 19, Aboul-Hosn discloses the invention substantially as claimed except for an annular projection on the outside surface of the flexible flange for the purpose of preventing fluid dripping to the central passage. Worner discloses (see Fig. 1) a thermometer having a skirt to prevent condensate which might gather on the exposed portion of the stem or instrument (see page 1, lines 1-10 and lines 35-45). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made by the applicant to integrate the edge or umbrella, as disclosed by Worner, to incorporate into the device, as disclosed by Aboul-Hosn to gain the advantages as suggested by Worner.
16. **Claim 20-25, 28-30 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aboul-Hosn in view of Worner (U.S. 2,320,993) and further in view of Freitas et al. (U.S. 5,330,497).**
17. Referring to **claims 20 and 25**, Aboul-Hosn discloses the invention substantially as claimed except for the cylindrical elongated member 12 has plurality of grooves on the outer surface that mating with the retention member wherein the grooves resists the retention member sliding in a proximal direction. Freitas discloses (see Figs 8, 9, and 10) a locking trocar sleeve having retention member 72 and the cylindrical elongated member 170 has plurality of grooves on the outer surface that mating with the retention member wherein the grooves resists the retention member sliding in a proximal direction (see col. 7, lines 9-45). Therefore, it would

have been obvious to one of ordinary skill in the art at the time the invention was made by the applicant to use the retention design, as disclosed by Freitas, to incorporate into the device, as disclosed by Aboul-Hosn because this will provide another failsafe feature beside suturing.

18. Referring to **claim 21**, Aboul-Hosn discloses (see Fig. 2A) outer surface of flexible flange 22 is adapted to fold in a proximal direction and radially inward during insertion of said port body.
19. Referring to **claims 22-24**, Aboul-Hosn discloses the cylindrical elongated member 12, 13 made of polymer or stainless steel (see col. 4, lines 25-30), thus the member 12 is capable adapted to maintain structural integrity in response to forces exerted by the body wall when said tubular section is angled within a narrow opening in the body wall.
20. Referring to **claims 28-30 and 32**, Aboul-Hosn discloses flexible flange 22, that made of silicone, is adapted to reduce in diameter when said port body passes through a narrow opening in the body wall (see Fig. 2A) and said flexible flange 22 has a frusto-conical shape with a proximally-concave outer surface and the flange includes an annular projection that projects radially outward wherein the projection is mating with the obturator 77 (see Fig. 3); obturator 77 having a rod-like section 75, tip 74, and handle 73 (see Fig. 2B); and a valve assembly 47 at the proximal end of cylindrical member 12 (see col. 4, line 12 to col. 6, line 45). Here it is noted that silicone material is a hydrophobic material. Adding weight to examiner

statement U.S. Patent No. 3,983,879 issued to Todd discloses silicone is a hydrophobic material (see col. 2, lines 43-45).

21. **Claims 26-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aboul-Hosn in view of Worner (U.S. 2,320,993) and further in view of Worner (U.S. 2,320,993).**
22. Referring to **claims 26-27**, the modified device of Aboul-Hosn discloses the invention substantially as claimed except for an annular projection on the outside surface of the flexible flange for the purpose of preventing fluid dripping to the central passage. Worner discloses (see Fig. 1) a thermometer having a skirt to prevent condensate which might gather on the exposed portion of the stem or instrument (see page 1, lines 1-10 and lines 35-45). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made by the applicant to integrated the edge or umbrella, as disclosed by Worner, to incorporate into the modified device, as disclosed by Aboul-Hosn to gain the advantages as suggested by Worner.
23. **Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Aboul-Hosn in view of Worner (U.S. 2,320,993) and further in view of Shikhman et al. (U.S. 5,423,796).**
24. Referring to claim 16, the modified device of Aboul-Hosn discloses the invention substantially as claimed except for a side port in fluid communication with said passage of the cylindrical elongated member. Shikhman discloses (see Fig. 1) a trocar system having side port 60 wherein the port 60 in fluid communication with

the central passage of the trocar sleeve 24 for the purpose of insufflation and desufflation (see col. 5, lines 1-5) Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made by the applicant to add the side port, as disclosed by Shikhman, to incorporate into the modified device, as disclosed by Aboul-Hosn to gain the advantages of insufflation and desufflation as suggested by Shikhman. Here it is noted that side port for insufflation and desufflation in a trocar system is old and well known in the art.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tuan V. Nguyen whose telephone number is 571-272-5962. The examiner can normally be reached on M-F: 9:00 AM - 5:30 PM.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, AnhTuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Tuan V. Nguyen
September 22, 2006


ANH TUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER
9/26/06.